

REMARKS

Claim 9 has been canceled. Claim 1 has been amended to recite that the nucleic acid has at least 95% sequence identity to the nucleotide sequence set forth in SEQ ID NO:1. Claim 21 has been amended to change its dependency to claim 1. New claim 29 has been added. Support for claim 29 can be found, for example, at page 5, lines 20-30 of the specification. No new matter has been added. Applicants respectfully request reconsideration and allowance of claims 1, 3-7, 10, 21, and 26-29 in view of the above amendments and following remarks.

Rejections under 35 U.S.C. §112, first paragraph

The Examiner rejected claims 1, 3-7, 9, 21, and 26-28 under 35 U.S.C. §112, first paragraph, for allegedly lacking written description. The Examiner asserted that “sequence identity alone does not describe the common attributes shared among the species of the claimed genus that is required for functional activity” and that “SEQ ID NO: 1 is not representative of sequences that differ from it.” The Examiner further asserted that “many of the elements recited in Table 1, are not further discussed in the specification as being required for activity of SEQ ID NO:1.” In addition, the Examiner asserted that the “importance of these domains to the functional activity of SEQ ID NO:1 is unknown.” Furthermore, the Examiner asserted that the domains of Table 1 are scattered throughout SEQ ID NO:1, and the specification “does not actually describe which of these sequences actually are required for transcriptional activity, or which ones confer seed and embryo specificity to SEQ ID NO:1.” The Examiner also asserted that fragments encompassed by claim 26-28 would not retain all of the domains and could not have the functional activity of SEQ ID NO:1.

Applicants disagree with the Examiner. Applicants will first address claims 26-28, which relate to fragments of SEQ ID NO:1 that are at least 500 nucleotides in length. All such fragments of SEQ ID NO:1 have literal written support in the sequence listing. That is, the claimed fragments of SEQ ID NO:1 require no more sequence information than is present in the sequence listing. Written description cannot be lacking for what is literally described. As is known in the art, fragments of SEQ ID NO:1 can be generated, for example, using partial or

complete digests with various endonucleases. Promoter activity can be routinely confirmed by expression assays, for example, as described in the specification at page 9, line 20 to page 10, line 11 and in Examples 3 and 4.

Nucleic acids having at least 95% sequence identity to the nucleotide sequence set forth in SEQ ID NO:1 also have sufficient written description in the specification. All of the species within the genus share a significant degree of partial structure (i.e., at least 95% of SEQ ID NO:1). With the aid of a computer, one of ordinary skill can easily and with 100% predictability envision every possible sequence that satisfies the criteria of the genus of claims 1, 3-7, and 21.

The specification also identifies a number of regulatory motifs in SEQ ID NO: 1 that are reported to be involved in promoting expression. The Examiner asserts that the "importance of these domains to the functional activity of SEQ ID NO:1 is unknown" and that "[t]here is nothing in the claims indicating that each of the domains listed in Table 1 are also to be present." However, the motifs identified in Table 1 are elements that have been identified in other promoters and assigned particular functions. See, for example, page 20, line 6 through page 22, line 24 of the specification and references cited therein. For example, SEQ ID NO:1 includes a CAAT-box motif, which helps define RNA polymerase binding site and enhance transcription, a TATA-box, which positions RNA polymerase II for transcription initiation, and a CTCATCTA motif, which is a transcription initiation sequence.

With respect to the (CA)_n element in SEQ ID NO:1, the Examiner asserts that this element "confers endosperm specificity" but the "working examples do not show endosperm specificity for SEQ ID NO:1." As indicated in the response of April 28, 2009, the (CA)_n motif is reported to be needed for endosperm and embryo specific expression. See, e.g., page 21, lines 13-15 of the specification. SEQ ID NO:1 also contains at least four motifs (e.g., the TGAC motif, RY-like motif, CANNTG motif, and AACACA motif) that are reported to confer seed-specific expression. See, page 20, lines 6-7 and lines 12-13, page 21, lines 1-2 and lines 8-9, and Table 1 of the specification. The data provided in Examples 3 and 4 demonstrate that SEQ ID NO:1 is useful, for example, for directing expression of a target nucleic acid in seeds and

embryos. See, for example, the results for pMB352 in Table 3, the results for pMB354 in Table 4, page 25, line 9 through page 26, line 4, and page 27, lines 9-24 of the specification.

While the specification identifies other motifs in SEQ ID NO:1 that have been reported to be involved in light regulation or responsiveness to a particular compound, claims 1, 3-7, 21, and 26-28 do not require the nucleic acid to be responsive to light or other compounds. Rather, claims 1, 3-7, 21, and 26-28 indicate that the claimed nucleic acids are capable of promoting expression in a plant cell of an operably linked heterologous nucleic acid.

With respect to claims 26-28, the Examiner asserted that "the nucleic acids encompassed by claims 26-28 could not have the functional activity of SEQ ID NO:1" as the "domains are scattered throughout the 2400 base sequence of SEQ ID NO:1." However, the CAAT-box motif, TATA-box, CTCATCTA regulatory motif, RY-like motif, CANNTG, TGAC, and AACACA motifs noted above are located within 500 nucleotides of each other in SEQ ID NO:1 (e.g., from nucleotides 2026 to 2376). As of the filing date of the present application, it was well known that substantial alterations could be made to a promoter sequence while retaining promoter activity. For example, Welsch *et al.* (*Planta*, 216:523-534, 2003 (copy enclosed)) describe the creation of multiple deletion fragments of an *Arabidopsis thaliana* phytoene synthase (*psy*) gene promoter. Piechulla *et al.* (*Plant Molecular Biology*, 38:655-662, 1998, (copy enclosed)) describe the deletion analysis of promoters of four tomato light harvesting complex (*Lhc*) genes. Such references are submitted as evidence that one of ordinary skill in the art would understand that promoter sequences can be altered and retain activity. Thus, based on the specification and the knowledge within the art, those of ordinary skill in the art would conclude that Applicant would have been in possession of the claimed genus of nucleic acids. In light of the above, Applicants respectfully request withdrawal of the rejections under 35 U.S.C. § 112, first paragraph, for lack of written description.

The Examiner rejected claims 1, 3-7, 9, 21, and 26-28 under 35 U.S.C. §112, first paragraph, for lack of enablement. The Examiner asserted that

The importance of the regions identified in Table 1 to the activity of SEQ ID NO:1 was not confirmed experimentally. Many of these elements are described as required for activities which the specification does not mention is possessed by SEQ ID NO:1. For

example, sequences are noted ABA-responsiveness; light regulation; an AP2-like binding consensus for Arabidopsis transcription factor RAV1; a motif in a soybean 7S globulin gene; gibberellin responsiveness; cis-elements found in phenylalanine ammonia lyase genes; elements for ethylene responsiveness. Yet the specification does not teach SEQ ID NO:1 as responding to light, ABA, gibberellin, or ethylene. An element, CA(n), is listed, which confers endosperm specificity, and which the working examples do not show for SEQ ID NO:1. A sequence is noted only for being present in an oleosin promoter. One domain is even described as "Unknown." The importance of these domains to the functional activity of SEQ ID NO:1 is unknown.

The Examiner further asserted that:

Further, while several domains are noted in Table 1 as conferring seed or embryo specificity, they are scattered throughout the 2400 base sequence of SEQ ID NO:1, and there is no indication as to whether they actually do confer seed and/or embryo specificity to the SEQ ID NO:1. The fragments encompassed by claims 26-28 would not be expected to retain the activity of SEQ ID NO:1, as they would not retain all of the domains recited in Table 1. In the absence of further guidance, undue experimentation would be required by one skilled in the art to determine which, if any, of the supposed regulatory regions mentioned in Table 1 are actually required for the transcriptional activity of SEQ ID NO:1. Undue experimentation would also be required to determine the 10% of the sequences of SEQ ID NO:1 that can be altered, and what to change them to, without affecting its transcriptional activity.

Applicants respectfully disagree.

Amended claim 1 indicates that the nucleic acid has at least 95% sequence identity to SEQ ID NO:1 and is capable of promoting expression of an operably linked heterologous nucleic acid in a plant cell. As previously indicated, one of ordinary skill in the art can determine if a nucleic acid has at least 95% identity to SEQ ID NO:1 and determine if the nucleic acid functions as a regulatory element without undue experimentation. For example, the specification indicates that BLAST2 sequences program can be used for calculating percent sequence identity. See, specification, at page 6, line 1 through page 7, line 23. With respect to claims 26-28, no sequence identity calculations are necessary as the claimed nucleic acids are fragments of SEQ ID NO:1 that are at least 500 nucleotides in length.

With respect to the (CA)n element in SEQ ID NO:1, the Examiner asserts that this is listed as conferring endosperm specificity "and which the working examples do not show for

SEQ ID NO:1.” As indicated in the response of April 28, 2009, the (CA)_n motif is reported to be needed for endosperm and embryo specific expression. See, e.g., page 21, lines 13-15 of the specification. In addition, SEQ ID NO:1 contains at least four motifs (e.g., the TGAC motif, RY-like motif, CANNTG motif, and AACACA motif) that are reported to confer seed-specific expression. See, page 20, lines 6-7 and lines 12-13, page 21, lines 1-2 and lines 8-9, and Table 1 of the specification. The data provided in Examples 3 and 4 demonstrate that SEQ ID NO:1 is useful, for example, for directing expression of a target nucleic acid in seeds and embryos. See, for example, the results for pMB352 in Table 3, the results for pMB354 in Table 4, page 25, line 9 through page 26, line 4, and page 27, lines 9-24 of the specification.

While the specification identifies other regulatory elements in SEQ ID NO:1 that have been reported to be involved in light regulation or responsiveness to a particular compound, claims 1, 3-8, 21, and 26-28 do not require the nucleic acid to be responsive to light or other compounds. Again, claims 1, 3-7, 21, and 26-28 indicate that the claimed nucleic acids are capable of promoting expression in a plant cell of an operably linked heterologous nucleic acid.

With respect to claims 26-28, the Examiner asserted that “the fragments encompassed by claims 26-28 would not be expected to retain the activity of SEQ ID NO:1 as they would not retain all of the domains recited in Table 1.” Claims 26-28 do not require the nucleic acid to have a particular activity other than being capable of promoting expression in a plant cell of an operably linked heterologous nucleic acid. Claims 26-28 also do not require the fragment of SEQ ID NO:1 to retain all of the motifs recited in Table 1. Fragments of SEQ ID NO:1 that are at least 500 nucleotides in length, however, can be produced that include a number of the motifs recited in Table 1. For example, a fragment of SEQ ID NO:1 can be produced that contains the CAAT-box motif, TATA-box, CTCATCTA regulatory motif, RY-like motif, CANNTG, TGAC, and AACACA motifs noted above. Furthermore, as discussed above, it was routine at the time of filing to generate and analyze promoter fragments.

In view of the routine nature of producing fragments of nucleic acids and assaying for function, no undue experimentation would be required to make and use the claimed nucleic

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acids, expression vectors, plant cells, and plants. Applicants respectfully request that the rejection under 35 U.S.C. §112, first paragraph, be withdrawn.

CONCLUSION

Applicants submit that claims 1, 3-7, 10, 21, and 26-29 are in condition for allowance, which action is respectfully requested. The Examiner is invited to telephone the undersigned agent if it is felt that such would advance prosecution of the application. Please apply any charges or credits to deposit account 06-1050.

Respectfully submitted,

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